

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re application of:

Madaline Chirica, et al.

Application No.: 10/720,026
(U.S. Pat. No. 7,422,743)

Filed: November 21, 2003

For: MAMMALIAN RECEPTOR
PROTEIN DCRS5; METHODS OF
TREATMENT

Examiner: J. Seharaseyon

Art Unit: 1647

Conf. No.: 3154

MAIL STOP: Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
INDICATED ON PATENT UNDER 37 C.F.R. § 1.705(d)

Sir:

1. This is a request under 37 C.F.R. § 1.705(d) for reconsideration of the patent term adjustment (PTA) of 575 days indicated on U.S. Patent No. 7,422,743 (issued Sept. 9, 2008). It is respectfully submitted that, in light of *Wyeth et al. v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008), Applicants be afforded a PTA of **956 days**.

2. Pursuant to 37 C.F.R. § 1.705(d), this Request for Reconsideration of Patent Term Adjustment is timely filed within two months of the Sept. 9, 2008, issuance of U.S. Patent No. 7,422,743. Applicants could not have raised the issues raised herein under 37 C.F.R. § 1.705 (b), *i.e.* between the Notice of Allowance and payment of the issue fee, because it was not possible to be certain of the PTO's final determination of the PTA until after the patent issued, since post-issue-fee delays by the Office could have changed the PTA, and because the opinion in *Wyeth et al. v. Dudas* had not been rendered.

3. In compliance with 37 C.F.R. § 1.705(d), Applicants submit herewith a "Statement of the Correct Patent Term Adjustment: Grounds Under 37 C.F.R. § 1.702 For the Adjustment (37 C.F.R. § 1.705 (b)(2)(i) to (iv))". Briefly, Applicants request that the published PTA be amended to add delay under §154(b)(2)(B), as cut-off by filing of an RCE, and in light

of an additional period of Applicant delay, as described in greater detail in the accompanying Statement.

4. In further compliance with 37 C.F.R. § 1.705(d), Applicants submit herewith the \$200 fee set forth in 37 C.F.R. 1.18(e) as required by 37 C.F.R. § 1.705(b)(1). Any additional fees may be charged to, or refunds credited to, DNAX Deposit Account No. 04-1239.

Respectfully submitted,

Date: 7 November 2008

By: /Gregory R. Bellomy/
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**STATEMENT OF THE CORRECT PATENT TERM ADJUSTMENT: GROUNDS UNDER 37 C.F.R.
§ 1.702 FOR THE ADJUSTMENT (37 C.F.R. § 1.705 (b)(2)(i) TO (iv))**

Sir:

1. This statement is being submitted in support of the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT INDICATED ON PATENT UNDER 37 C.F.R. § 1.705(d)" to which this statement is attached.

37 C.F.R. § 1.705 (b)(2)(i)

2. The patent term adjustment (PTA) shown on U.S. Patent No. 7,422,743 is 575 days. Applicants believe that this determination of 575 days is in error, due to the Office's improper interpretation of the PTA provisions as discussed in *Wyeth et al. v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008). Specifically, the Office improperly limited PTA to either the PTA as calculated under 35 U.S.C. §154(b)(1)(A) or as calculated under 35 U.S.C. §154(b)(1)(B), but not both. 69 Fed. Reg. 34238 (June 21, 2004). However, as discussed in *Wyeth et al. v. Dudas*, the statute requires that PTA may comprise contributions from both 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B), and that the Office's interpretation of the statute was erroneous to the extent that it considered any delays within the first three years after filing the application to "overlap" with delays under §154(b)(1)(B) after three years from the filing of the application. According to the Court, no delay accumulated within the first three

years after the filing date can be said to "overlap" with delays under §154(b)(1)(B), which by definition do not arise until after three years from the filing date. It is respectfully submitted that the correct patent term adjustment under 37 C.F.R. § 1.702, as calculated under the analysis of *Wyeth et al. v. Dudas*, is **956 days**.

37 C.F.R. § 1.705 (b)(2)(II)

3. The basis on which Applicants seek adjustment is as follows, which is based on the analysis laid out in *Wyeth et al. v. Dudas*, rather than the Office's analysis laid out in 69 Fed. Reg. 34238 (June 21, 2004). Accordingly, the net PTA comprises accumulated PTA arising from both 35 U.S.C. §154(b)(1)(A) and (B), and deducting any periods of time in which Applicants failed to engage in reasonable efforts to conclude prosecution (35 U.S.C. §154(b)(2)(C)(i)).

A. The application was filed on November 21, 2003.

B. A Restriction Requirement was mailed September 26, 2006, which was 613 days after the date that was 14 months after the filing date.

C. An Office Action was mailed Feb. 27, 2007.

D. Applicants filed a Response to the Office Action on Tuesday, May 29, 2007, the day after Memorial Day, incurring a 2 day delay.

E. A first Notice of Allowance was sent on January 31, 2008.

F. Applicants filed an RCE with an IDS on February 7, 2008.

G. A second Notice of Allowance was sent on April 8, 2008, 62 days after the filing of the RCE.

H. Applicants filed an Amendment after Notice of Allowance Under Rule 312 on June 4, 2008.

I. The Office mailed a Response to the Rule 312 Amendment on July 9, 2008, 36 days after the filing of the Rule 312 Amendment.

J. The PTA listed on the face of U.S. Patent No. 7,422,743 when it issued on Sept. 9, 2008, was **575 days** (apparently calculated as 613 days – 2 days – 36 days). This PTA was calculated under 35 U.S.C. §154(b)(1)(A), and excluded any PTA calculated under 35 U.S.C. §154(b)(1)(B) under the Office's interpretation of the PTA rules and statutes. The PTA also appears to overlook the 62 day period of Applicant delay explained at "G" above.

K. In light of the analysis laid out in *Wyeth et al. v. Dudas*, the correct PTA should have also included delay under 35 U.S.C. §154(b)(1)(B), and should have included the 62 day period of Applicant delay.

i) Delay under §154(b)(1)(B) is the period starting three years after the filing date and ending on the issue date, except that such PTA no longer accrues after the filing of an RCE (35 C.F.R. §702(b)(1)). Accordingly, for the present application, the resulting §154(b)(1)(B) period runs from the period starting three years after the filing date (November 21, 2006) and ending on the date the RCE was filed (February 7, 2008), or **443 days**.

iii) The resulting net PTA is the sum of the delays under §154(b)(1)(A) and (B), less Applicant delays, or $613 + 443 - 2 - 62 - 36 = \mathbf{956}$ days.

L. Accordingly, Applicants request that the PTA for U.S. Patent No. 7,422,743 be amended to **956 days**.

37 C.F.R. § 1.705 (b)(2)(iii)

4. The present application is not subject to a Terminal Disclaimer.

37 C.F.R. § 1.705 (b)(2)(iv)

5. Items 3(C) – 3(I) *supra* outline Applicant delays in the prosecution of the present application. 37 C.F.R. § 1.702(c)(10)(i).

A first period of 2 days began on the day after the date that was three months after the mailing of the first Office Action (May 27, 2007) and ended on the day when the Response was filed (May 29, 2007). 37 C.F.R. § 1.704(b).

A second period of 62 days began on the date of filing of the RCE (February 7, 2008) and ended on the date the second Notice of Allowance was mailed (April 8, 2008). 37 C.F.R. § 1.704(c)(10)(i).

A third period of 36 days began on the date of filing the Amendment Under Rule 312 (June 4, 2008) and ended on the date Response to the Rule 312 Amendment (July 9, 2008). 37 C.F.R. § 1.704(c)(10)(i).

In summary, Applicants request that the PTA of 575 days listed on U.S. Patent No. 7,422,743 be amended to add delay under §154(b)(2)(B), and in light of an additional period of Applicant delay. Applicants respectfully request a favorable decision on the patent term adjustment of **956 days** in this case.

Respectfully submitted,

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